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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,868	04/25/2007	Jean-Louis Viovy	121697	5953
25944 7590 06/23/2008 OLIFF & BERRIDGE, PLC P.O. BOX 320850			EXAMINER	
			WHISENANT, ETHAN C	
ALEXANDRIA, VA 22320-4850			ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
			06/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/582.868 VIOVY ET AL. Office Action Summary Examiner Art Unit Ethan Whisenant, Ph.D. 1634 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 June 2006. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-35 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) 1-9.11-13.15-19.27-31 and 33-35 is/are allowed. 6) Claim(s) 10.14.20-26 and 32 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 14 June 2006 is/are; a) ⊠ accepted or b) Tobjected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date 11/2/2006; 6/18/2007; and 10/22/2007.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. \_\_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application



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## Non-Final Action

The applicant's Preliminary Amendment filed 14 JUN 06 has been entered.
 Following the entry of the Preliminary Amendment, Claim(s) 1-28 and 30-35 is/are pending.

#### SEQUENCE RULES

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

## 35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

# Claim Rejections - 35 USC § 101

4. Claim(s) 25-26 is/are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claim 25 is nonstatutory because the "use of" is not a patentable category under 35 U.S.C. § 101.

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## 35 USC § 112- 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

# CLAIM REJECTIONS under 35 USC § 112-2ND PARAGRAPH

 Claim(s) 10, 14, 20-24 and 32 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10,14 and 20 are indefinite because of the use of the phrase "preferably ...". The use of exemplary claim language makes these claims indefinite. See the MPEP at 2173.05(d). It is well established that the description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences lead to confusion over the intended scope of a claim. Ex parte Hall, 83 USPQ 38 (Bd. App. 1949).

In Claim 21 should not the phrase "chosen in the group" be "chosen from the group".

Claim 23 is indefinite because the phrase "the channel wall" lacks proper antecedent basis.

Claim 32 is confusing because it is unclear what is intended by the limitation which reads "and a pair of molecules or groups acting as a DNA probe called "molecular beacons" Please clarify.

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## 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another field in the United States before the invention by the applicant for patent by 2(a) patent grained on an application for patent by another field in the United States before the invention by the applicant for patent, except that an international application filled under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filled under the United States only if the international application designated the United States only in the English language that the United States only in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an intensitional application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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# CLAIM REJECTIONS UNDER 35 USC § 102

9. Claim(s) 27-28 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Cosgrove et al. [US 4,166,118 (1979)].

Cosgrove teach a 1% nicotinamide adenine dinucleotide solution which is a composition including a compound able to undergo specific base pairing interaction at a concentration of at least 1g/L and a least a liquid separating medium. By definition a 1% solution contains 1g of solute in 100 ml solvent. Thus the 1% nicotinamide adenine dinucleotide solution is actually present at 10g/1000ml (i.e. 1 L).

#### ALLOWARI E SUBJECT MATTER

- 10. Claim(s) 1-28 and 30-35 would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101 and 112 set forth in this Office action bacause the prior art recond, if considered individually, do not teach or if considered in combination do not reasonably suggest the method/ compositions recited in Claims 1-28 and 30-35.
- ▶It is noted that in the parent application (PCT/IB04/04171) the examiner for the international searching authority found that Claims 1-3, 6-12, 15-17, 19-24, 27-31 and 33 lacked novelty over Acharya et al. [WO99/10369 (1999)]. The US examiner in instant application does not agree with the findings of the international authority because Acharya et al. do not teach a composition including at least a compound able to undergo specific base pairing at a concentration of at least 1g/l and at least a liquid separating medium or a method of assaying for a mutation wherein said composition is utilized. Furthermore, Acharya et al. teach a section on pp. 62-63 that recites "G/T mismstch binding by hMSH2:hMSH6 is a model for mismatch recognition" However, this examiner, in contrast to the examiner for the international authority, has been unable to find a teaching in Acharya et al. wherein the G/T recognition assay is carried

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in a presence of a compound able to undergo specific base pairing at a concentration of at least 1g/l.

▶ The examiner invites the applicant to review Acharya et al. and the comments of the examiner for the international authority, as well as, the comment recited above, and to, if desired, make their own traversal of Acharya et al. in order to clarify the record.

#### CONCLUSION

- 11. Claim(s) 1-9, 11-13, 15-19, 30-31 and 33-35 is/are allowable while Claim(s) 10,14. 20-28 and 32 is/are rejected and/or objected to for the reason(s) set forth above.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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# **EXAMINER SEARCH NOTES**

# 07 JUN 08 - ECW

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s): e.g. Voovy J?/au

Nucleic

DNA or RNA or PNA

Hybridization

Deletion or Insertion or Mutation

SNP

Heteroduplex or Homoduplex

Nucleotide\$ solution\$

Dinucleotide\$ solution\$

Electrophoresis

capillary electrophoresis

Heteroduplex analysis

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# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- 1. This application clearly falls to comply with the requirements of 37 C.F.R. 1.821-1.825.
   Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- □ 7. Other:

#### Applicant Must Provide:

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- An <u>initial</u> or substitute paper copy of the "Sequence Listing", as well as, an amendment directing its entry into the specification.
- A statement that the content of the paper and computer readable copies are the same and, where
  applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or
  1.825(b) or 1.825(d).

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#### CONCLUSION

1. Claim(s) 4 is/are rejected and/or objected to for the reason(s) set forth above.

 Claim(s) 31-32 is/are allowable while Claim(s) 1-30 and 33-44 is/are rejected and/or objected to for the reason(s) set forth above.

3. Claim(s) 1-4, 6-10, 12-13, and 15-17 is/are allowable for the reason(s) of record and have now been renumbered as Claims 1-14.

2. Final Paragraph Final

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/ Primary Examiner Art Unit 1634 Application/Control Number: 10/582,868

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# **EXAMINER SEARCH NOTES**

# 04 MAR 08 - ECW

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s): e.g. Thompson A?/au

Circularizable probe

Circularized probe

Cleavage or cleave

Mass tag?

Mass spectrometry

Primer extension

5' (nuclease or exonuclease

Taqman

Taqman Mass tag? and/or Mass spectrometry